

REMARKS

I. INTRODUCTION

The Office Action mailed July 31, 2008, has been carefully considered. In response thereto, this paper, which is believed to be fully responsive to the Office Action, is being submitted.

II. STATUS OF THE CLAIMS

Claims 1-8 and 15-22 are pending in the application (claims 9-14 and 23-42 have been withdrawn in response to a restriction requirement issued by the PTO in a previous Action). Claims 6 and 20 have been cancelled. No claims are being amended. No new claims have been added. Thus, upon entry of this paper in the record, claims 1-5, 7, 8, 15-19, 21, and 22 will be pending.

III. SUMMARY OF THE OFFICE ACTION

In the Office Action, the Examiner has rejected all of the claims under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Pub. No. 2001/0031999 to *Carter et al.* in view of U.S. Patent No. 5,324,317 to *Reiss* and also in view of U.S. Patent No. 5,643,330 to *Holsheimer et al.* The Examiner also states that the previous arguments submitted to the PTO on April 24, 2008, are moot because the present rejection of the claims is based on new prior art not previously relied upon by the Examiner.

It is noted that the Office Action Summary sheet indicates that the Office Action is "non-final"; however, the Detailed Action indicates that the Office Action is "final." In view of the fact that the Office Action is the first action after the filing of a Request for Continued Examination (RCE), it is respectfully submitted that the Office Action should be non-final. That was confirmed in an interview with the Examiner shortly after receipt of the Office Action (in which only the status of the Office Action was discussed).

IV. THE REJECTIONS OF THE CLAIMS

A. Analysis of Prior Art

In the Office Action, the Examiner has rejected all of the pending claims under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Pub. No. 2001/0031999 to *Carter et al.* in

view of U.S. Patent No. 5,324,317 to *Reiss* and also in view of U.S. Patent No. 5,643,330 to *Holsheimer et al.* In particular, with regard to independent claims 1 and 15, the Examiner contends that *Carter* discloses every feature recited in those claims except for "at least two pairs of implantable electrodes," but that *Reiss* teaches that "it is known to use at least two pairs of electrodes in interferential current treatments [citing Col. 2, lines 27-38] for providing the predictable result of providing optimization of the stimulation at the center," and *Holsheimer et al.* teaches "an interferential spinal cord stimulation system with implantable electrodes for providing the predictable results of decreasing the power consumption of the device by placing the electrode on the actual stimulation site, as well as ensuring proper placement of the electrodes in chronic stimulation patients." For the reasons set forth below, it is respectfully submitted that the Examiner has not established a *prima facie* case of obviousness, and Applicant therefore traverses the rejection of the claims.

At the outset, and contrary to the Examiner's contention, it is submitted that the combination of references do not disclose the use of a beat frequency caused by paired electrodes implanted in the dura matter of an epidural space. As stated in a previous submission to the Patent Office, *Carter* does not fairly disclose or suggest using pairs of electrodes in the same configuration as recited in the claims, including using pairs of electrodes that are implanted in the dura matter of an epidural space. Moreover, even if *Carter* does form a beat frequency between paired electrodes, which Applicant denies, *Carter* does not form a beat frequency as a result of interference between a first frequency from a first pair of electrodes and a second frequency from a second pair of electrodes. That is, *Carter* does not disclose the interference of a first frequency with that of another frequency to form an additive beat frequency.

In support of the above assertions, submitted concurrently herewith is a Declaration of William Carroll, which demonstrates that *Carter* does not disclose producing a beat frequency.

Likewise, *Holsheimer et al.* does not disclose using interferential current to produce a beat frequency. *Holsheimer et al.* states that "when the pulses given by the stimulator channels alternate in time and have sufficient amplitude and duration, overlapping areas of stimulation of the spinal area can be obtained. In the overlapping areas of stimulation, the frequency of stimulation is double the frequency of the pulses given by each of the stimulator channels separately." That is different than the current invention in which an interferential

current is set up between two circuits that are arranged in a cross-pattern on the subject's targeted area of stimulation. Where the circuits superimpose in a cross-pattern, the resultant beat frequency will be the difference between the frequencies of the two circuits and the amplitude will be additive and greater than either circuit alone. As noted in the application, interferential current allows improved directional control and depth of penetration in comparison to other stimulation techniques, like those described in *Holsheimer et al.*

While it may have been obvious to implant electrode pairs in the dura matter of a patient's back and stimulate the same using electrical current, it is an altogether different proposition to conclude that the degree and amount of time of pain relief observed by the present invention would have been obvious, or that the inherent problems using implanted electrodes can be solved simply by using combinations of prior art techniques. As described in the Declaration of Carroll, the efficacy of existing systems has not been established, nor have the problems associated with existing systems been overcome like the present invention. Thus, one cannot merely combine prior art references and assume that the combination will actually work as intended.

Moreover, the Examiner's design incentive argument that the combination would have been desirable due to "decreasing the power consumption of the device by placing the electrode on the actual stimulation site, as well as ensuring proper placement of the electrodes in chronic stimulation patients" does not consider the fact that one of ordinary skill in the art would have looked at whether the device works in the first place before considering power consumption and placement. In any case, interferential current consumes relatively more power than a typical SCS system. The system disclosed in *Reiss* with the SCS system disclosed in *Holsheimer et al.* would yield a system that would not be able to meet the standard of care due to power requirements.

Finally, the general belief by those of ordinary skill in the art at the time of filing the present application was that SCS techniques for the treatment of intractable pain syndromes generally did not meet clinical outcomes even several decades after the concept of using SCS was first published in 1967. The Declaration of Carroll demonstrates that there has existed a long-felt need for a device according to the present invention that solves one of several known problems that the present invention solves, in particular the problem of effectively treating both axial and radiating extremities pain, as opposed to just positively treating radiating

extremities pain with no positive outcome for axial pain.. Such evidence of a long-felt need for the present invention underscores the nonobviousness of the invention.

B. Joint Inventorship

In the Office Action, the Examiner notes that the application currently names joint inventors, and consequently the Examiner presumed that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

The present application should have only listed one applicant—William Carroll—as the sole inventor. Papers to correct inventorship were previously submitted to the PTO in connection with this application.

C. Cancelled Claims

With regard to claims 6 and 20, those claims have been cancelled without prejudice as to any rights to re-file those claims in a separate divisional application at a later time. The claims have not been cancelled in response to any rejection or objection to the claims.

V. CONCLUSION

Consequently, in view of the foregoing discussion and present amendments, it is respectfully submitted that this application is in condition for allowance. An early and favorable action is therefore respectfully requested.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (000309-00053). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, it is hereby petitioned under 37 C.F.R. §1.36 (a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized above.

Respectfully submitted,

BLANK ROME LLP

By: /Michael C. Greenbaum/ WCG
Michael C. Greenbaum
Reg. No. 28,419

600 New Hampshire Ave., N.W.
Washington, D.C. 20037
Telephone: (202) 772-5800
Atty. Docket No.:
Date: November 14, 2008
MCG/BWH/rrs